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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,990	02/20/2002	Buddy D. Ratner	920010.40001	1736

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EXAMINER	
PADGETT, MARIANNE L	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,990	RATNER ET AL.	
	Examiner	Art Unit	
	Marianne L. Padgett	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-49,51-53,56-73,75-81 and 84-96* is/are pending in the application.

4a) Of the above claim(s) *70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-49,51-53,56-69,71-73,75-81,84-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claim 85, in line 2 of the scanned copy has a 'dash' informally inserted before "a" in "-a controlled". The examiner suspects that this is are artifact of copying or scanning or the like, but it is in the official copy of the 7/26/04 amended claims, hence needs correcting.

2. Claims 49 & 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment to claim 49 does make the relationship clearer, however "solvents" implies solution of something solvated, and it remains unclear how this applies to a solvent being introduced in to a vacuum system with molecules that are already ionized. While the examiner suspect's molecules to be ionized are solvated in a solvent, that is to be separated after both are vaporized or atomized, this is NOT what's claimed.

The meaning of claim 87 is unclear; as it's uncertain how manipulating the object is intended to relate to the "...pumped interface". Is movement of the object required, if so how; or is the object manipulated by effecting the atmosphere and thus the form of the deposit by the ionized molecules on its surface? The meaning is ambiguous, since what effects occur due to the manipulation via vacuum are not specified. Alternately, does this claim mean that the object being processed is NOT in the vacuum chamber at the start of the deposition (so what's being deposited on?) and is moved in or out while deposition is occurring? This option has a few logic problems, or missing pieces of information or context. Claim 88 suggest that this latter option is intended, but has not been provided with sufficient context to be meaningful.

3. In new claim 88, it is noted that while "first...chamber" and "second treatment chamber" imply an order, the limitations of the claims do not require the implied order, nor that

the first and second labeled chambers are necessarily different chambers. Since claim 89, requires the depositing in the "second" chamber to be done prior to the plasma treating in the "first", it is clear no order can be considered intended by the labels given the chambers.

4. Applicant's amendments have corrected previously rejected 112 problems, except as noted above.

5. Claims 42-53, 56-69,71-73,75-81 &84-96 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While applicants stated that no new matter was added to the claims (p. 9 of 7/26/04 response, in Remarks), no attempt to cite support for new limitations was found.

In reviewing the specification, while no reference to use of a beam of ionized molecules was found, the elected option of electrospraying was illustrated in figures 2-3, discussed on pages 4-9 of the specification, using charged droplets introduced into the deposition system in such a configuration that would inherently form a beam, hence for the elected option of electrospray, the claimed beam appears to be supported, but not for general deposition, i.e. ion beams in general, nor for all the non-elected options of claim 45, hence while partly supported, New Matter appears also to have been included due to the broad scope of the claims.

With respect to new claim 88, no disclosure of an apparatus that has separate chambers for plasma treating and depositing ionized molecules was found, nor any disclosure of treating a portion (first) of the substrate in the vacuum environment, while part of that substrate (second) is

still out side the vacuum system was found. Page 10, lines 4-7, discuss use of differential pumping to permit introduction of an object form the ambient atmosphere into the apparatus for processing, but does not provide the details claimed, nor hinted at for introducing the object while simultaneously processing it with plasma or deposition, as in claims 87 or 88-92. Thus, these claim appear to include New Matter.

With respect to new claims 93-94, while deposition of ionized molecules is discussed throughout the specification the examiner failed to find a teaching of the requirement that these ionized molecules be "intact", i.e. large molecules such as biomolecules or enzymes, have not lost so much as a proton (H) when being ionized (gaining or losing electrons). Therefore, New Matter appears to have been introduced by this requirement.

New claim 95, appears directed to creating an ion beam from ionized molecules in a gas, such as would read on a remote plasma source, and separating the gas from the ionized molecules, but no such system was found described in the specification, as the electrospray system, the only one described in detail, uses a solution in which the ions are initially generated in spray capillary (604), thus no support for this claim was found, so it too appears to encompass New Matter.

6. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179

USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to "All of the above referenced..." (p.11, lines 9-13) is improper because it is improper to incorporate other references indiscriminately, and to supply any essential teachings from non-U.S. patent references. Should any of the above-cited new matter have been intended to be supplied from this all-encompassing incorporation of 8 or so references, it is improperly done.

7. The amendments, specifically relating to the requirement of a beam of ionized molecules, i.e. a molecular ion beam, have removed the rejections based on the various Ratner references, as all their ionized molecules were plasma derived, not from beams. The Schram et al reference, while discussing various ion sources including plasma and ion beams, does not have any explicate teaching on combining successive treatments of the two types as claimed, hence this art rejection is also removed.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 42-43, 46, 56-57, 68, 76, 79-80 & 86 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Andra (5,645,897).

Andra teaches surface modification in vacuum, that includes etching, coat or depositing where substrates may be metal, semiconductive (Si), insulating (SiO_2 or Al_2O_3) and where a reactive gaseous fluids that may be a molecular ion beam is supplied to that surface and activation energy supplied thereto via a plasma (highly charged ions and relatively low energy) directed at the surface. See the abstract; figures, esp. 1 & 3; col. 3, lines 59 – col. 4, line 35^+ for highly charged low energy ions activating of the surface for coating or etching purposed; col. 6, lines 24-67; col. 7, lines 3-7 (beams of gas or vapor), lines 8-15 (may first clean the surface with the highly charged ions before successive steps) and lines 20-25 (improved productivity for PECVD and IACVD processes); and claims 1, 3-5, 7-15 and 17 (masked for patterning).

10. Claims 47-48, 51, 52, 58, 61-64, 75-76, 78, 87 and 93-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andra.

Andra does not explicitly set out the details of these claims, however they concern general standard procedure for forming and controlling ion beams or plasmas, which would have constituted standard operating procedure or typical equipment employed to control molecular ion beams or plasmas as taught and provide reproducible results. Also, in support of this, it is noted that Andra's alternative to using a plasma for activation is use of an ion beam also highly charged low energy, but for this beam controls and ion optics as claimed are discussed, hence it would have been further obvious to apply such basic ion beam generation and control procedures as used in the activation beam, for the fluid stream that may be a molecular ion beam, as it would also need to be guided and focused in order to be employed as taught.

While Andra does not provide a specific example of reagents used within the plasma, when that option is used with a molecular ion beam, nor a listing of gases for general use in their process, their examples do employ gases such as N_2 or Ar or SF_4 or CCl_4 in various reactions, hence it would have been obvious to use like gases in the alternative options as taught in order to effect analogous results, due to the suggestion of their use by the alternative examples.

While Andra does not discuss taking their substrate in and out of the treatment area, they do discuss differential pumping for controlling pressure in various parts of their apparatus, and as the substrate is not originally nor after treatment part of the apparatus, one of ordinary skill would assume it is put in and taken out of the chamber which is under vacuum, hence must at some point before and after treatment, go though manipulation to move it and to bring some portion of the apparatus in which it resides up to atmospheric pressure in order to remove it. Where ever that is might be considered an "interface".

11. Hansen is of interest to the state of the art, as it teaches spray coating medical devices, such as stents, catheters, cardiovascular sutures, etc., that may be made of metallic (stainless steel) or polymeric materials. The spraying technique includes biological reagents as contemplated in a solvent, electrically charging this coating formulation and creating therefrom changed droplets to be deposited on an electrically grounded substrate that guides the charged particles thereto. After coating, a sterilization process is recommended and may be done via a gas plasma treatment (abstract; figures; col. 2, lines 28-42; col. 3, lines 5-27; col. 4, lines 13-65; col. 5, lines 45- col. 8, line 17^{+}; col. 10, lines 1-5 and claims. However, Hansen has no discussion concurring what pressure is used during any of the processing, hence probably does not employ vacuum.

12. Claims 42, 46, 56, 61, 67, 80 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Noda et al (5,374,613).

Noda et al teach a process of depositing superconductive thin films under vacuum on various substrates including epoxy, where the combination of supplying excited oxygen that has been produced via (RF) discharge (i.e. is equivalent to the claimed plasma), with a beam supplying the rest of the precursors for the superconductor film, inclusive of ion beam, molecular beams and cluster ion beams. The taught cluster beams would have inherently been inclusive of molecular components due to the nature of cluster ion beams, thus reading on the claimed "beam of ionized molecules". Alternatively, given teachings of ion beams, molecular beams and cluster ion beams, it would have been obvious to one of ordinary skill in the art to employ molecular ion beams as the cluster beams are generally suggestive of molecular states, and the alternatives

include both ions and molecules. See the abstract; Fig. 12 (also 9); col. 2, lines 24-62; col. 4, lines 5-26; col. 8, lines 52 – col. 9, line 21 (includes masking to pattern); and claims 1-4.

13. Claims 47-48, 51-52, 62-63, 77-78, 87 & 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda et al.

While Noda et al does not provide details on the formation of the ion cluster beams, nor their guidance, they are shown directed from beam emitting device (6) to the substrate with the coil 33 that creates the RF discharge, which excites the oxygen. This coil would act as an additional guiding means, such that the potential of the coil as focusing or acceleration or guidance, as the ion beam and the discharge must have complementary (e.g. opposite) potentials for the taught process to be functional, so would effect the path already, hence optimizing with it would have been efficient use of required features. The steps of claim 95 to produce an ion beam are merely typical procedure therefore, as part of producing one is extracting the ions from the gaseous ionized source material, generally a plasma, which is a mixture of variously charged ions, electrons, a variety neutral atoms, molecules or fragments depending on precursor materials. Note measuring ones ion beam at sometime in the process and/or development thereof is matter of competent workmanship, in order to maintain quality and be able to reproduce results.

14. Other new art of interest includes Akizuki et al (6,797,334 B2), which teaches creation and use of ion cluster beams for input into vacuum for their film formation, with discussion of molecules, but does not combine with plasma treatments; Koh et al (6,300,641 B1), who teach surface modification of polymers and other materials for effects as claimed using ion beams that may be Ar^+ or O_2^+, etc., where end use in medical fields is suggested (col. 7), but

does not mention use in conjunction with plasma treatment for its various uses, nor does it exclude such; Ouderkirk et al (5,389,195), who teaches the use of a co-axial plasma gun, employing gas, liquid or solid source material to create ionized streams of treatment material for modifying surfaces, such polymers, but does not give a clear indication of whether or not their resultant beam may have molecular ions: and Ferralli (4,474,827), who teach an ion beam (IB) that may use monomers as its ion source material for deposition, as well as having more monomers in the deposition area that are ionized by the IB, but does not discuss whether the potentials that cause acceleration in the deposition zone, also will sustain a plasma there.

15. Claims 42-43, 45-49, 51-53, 56-65, 67-69, 71-73, 75-81, 84-87 and 93-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galin et al (5,944,753), as discussed in section 12 of paper mailed 4/26/04, in view of Morozov et al (6,350,609 B1).

Applicant's claims have been amended to require deposition from a beam of ionized molecules, and while there was no discussion of beams found in the specification, it was submitted by the examiner that the taught electrospray apparatus as depicted in Fig. 2-3, effectively showed or illustrated a beam, so this limitation was deemed supported for electrospray, and by the same logic, any electrospray of similar configuration will be considered to read on the claimed beam, whether or not beams are discussed.

In Morozov et al (609 B1), see the abstract; Figures 1, 3-4, 6-7, 9, 16, 20-21, 24-25, 32-34 for configuration, masking, substrate movement and biasing or grounding; summary for electrospray deposition of various biomolecules, such that they retain their functional properties (implies intact); col. 7, lines 35-53; col. 9-10 for various focusing, electrostatic lens, masking, application of voltage to substrate, etc., limitations used for electrospraying; col. 15 for use of

"dry" gas when forming electrospray from diluted bimolecular solutions in order to concentrate, col. 16, lines 26^{+} for further conditions, such as faster drying (line 36), use of sugars as protective reagents in spray (line 38 and 65); col. 18 of the advantages of electrospray over other techniques and for itself, such as the ability to apply depositions of charged molecules and cluster under vacuum and its patterning ability (lines 58-68).

It would have been obvious to apply Morozov et al's electrospray technique for the generic spray techniques suggested by Galin et al, for reasons as previously discussed, and since Morozov et al (609 B1), shows its effectiveness and desirability with saccharides, and further nothing that its is compatible with Galin et al's proceeding step of plasma pretreatment, as it may be performed in vacuum following the previous treatment, thus potentially advantageously simplifying the production line.

16. Claims 42-43, 45-49, 51-53, 56-69, 71-73, 75-81 & 84-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hostettler et al (5,849,368) as applied in section 13 of the action mailed 4/26/04, and in view of Morozov et al (609 B1) discussed above in section 15.

Reasons for combination with Morozov et al are the same as given above. Further note that Hostettler et al's suggested medical devices include those that have elongated structures, such as catheters, hence it would have been further obvious to treat them such the entire length is pulled through the various treatment stages until the desired length of surface is treated, as such is a conventional means of effecting "continuous" substrates.

17. Claims 42-49, 51-53, 56-69, 71-73, 84-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb et al (5,824,049) in view of Morozov et al (609 B1).

Ragheb et al is coating implantable medical devices that may be polymeric or metal such as stainless steel, and elongated structures such as stents, catheters, vascular grafts, etc. A series of layers are taught, with an initial optional vacuum vapor deposited polymer layer, that is suggested to be plasma treated to improve adhesion before the following deposition of a bioactive material that may be various enzymes or a mucopolysaccaride, such as heparin. The bioactive material may be deposited by a variety of convenient ways, where spray coating and electrostatic deposition are suggested. Thereafter a porous polymeric layer is deposited, which may be vapor deposited like the first or plasma deposited. It is further taught to be desirable to plasma treat this top polymeric layer to improve its biocompatibility by altering its surface energy, which is suggestive of the claimed functionalization. See the abstract; summary, esp. col. 3, lines 10-35^{+}; col. 4, lines 29-39 and 51; col. 5, lines 1-32; col. 6, lines 38-59; col. 7-8, esp. col. 7, line 34-50, and col. 8, line 22-34; col. 10, line 39-51; col. 14, line 50-col. 15, line 13; and col. 17, lines 24 – col. 18, line 54.

Ragheb et al does not provide specific claimed details on electrospraying, however it would have been obvious to use the specific electrospray techniques of Morozov et al (609 B1) for reasons as stated above, further noting that as the process both before and after the deposition of the bioactive material require the use of vacuum, that Morozov et al's teaching of use in vacuum provides a significant advantage of not needing to let up and pump back down to vacuum pressures. Above obviousness of sequence treatment of long substrates is also applicable here.

18. Applicant's arguments filed on 7/29/04 and discussed above have been fully considered but they are not persuasive.

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on Monday through Friday about 8:30 AM to 4:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive Beck can be reached on (571) 272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padgett/LR
November 23, 2004
December 17, 2004

MARIANNE PADGETT
PRIMARY EXAMINER

1. Claim 85, in line 2 of the scanned copy has a 'dash' informally inserted before "a" in "-a controlled". The examiner suspects that this is are artifact of copying or scanning or the like, but it is in the official copy of the 7/26/04 amended claims, hence needs correcting.

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3. In new claim 88, it is noted that while "first...chamber" and "second treatment chamber" imply an order, the limitations of the claims do not require the implied order, nor that

the first and second labeled chambers are necessarily different chambers. Since claim 89, requires the depositing in the "second" chamber to be done prior to the plasma treating in the "first", it is clear no order can be considered intended by the labels given the chambers.

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In reviewing the specification, while no reference to use of a beam of ionized molecules was found, the elected option of electrospraying was illustrated in figures 2-3, discussed on pages 4-9 of the specification, using charged droplets introduced into the deposition system in such a configuration that would inherently form a beam, hence for the elected option of electrospray, the claimed beam appears to be supported, but not for general deposition, i.e. ion beams in general, nor for all the non-elected options of claim 45, hence while partly supported, New Matter appears also to have been included due to the broad scope of the claims.

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